REMARKS

THE AMENDMENTS

Applicant has amended Claim 8 to improve its form and has amended Claim 19 to more distinctly point out the claimed invention. Applicant has canceled claim 4. Claims 2-3, 8-10, 14, and 19 are pending in the present application.

These amendments are made without prejudice and without waiver of applicants' right to pursue any canceled subject matter in one or more applications claiming priority herefrom under 35 U.S.C. § 120.

These amendments add no new matter.

Applicants request reconsideration of the above-identified application, in view of the above amendments and the following remarks.

REJECTIONS

35 U.S.C. §112, Second Paragraph

Claims 8 is rejected under 35 U.S.C. § 112, second paragraph, as "indefinite." Office Action, page 3.

The Examiner asserts that it is indefinite which "one or more markers, 'the polymorphous DNA microsatellite marker' is being referred to." Applicants have amended claim 8 in accordance with the Examiner's recommendation,

to recite "...said one or more polymorphous DNA microsatellite markers..."

Accordingly, applicants request the Examiner withdraw this rejection.

35 U.S.C. §103(a)

Claims 2, 3, 8-10, 14, and 19 stand rejected under 35 U.S.C. 103(a) as "unpatentable" over Allione et al. ("Allione") in view of United States patent 5,945,522 ("Cohen") and United States patent 5,624,819 ("Skolnick").

The Examiner contends that it would have been obvious to one of ordinary skill in the art at the time of filing of the instant application to combine the teaching of Allione with Cohen and Skolnick to arrive at the method of the present application. Applicant traverses.

Applicant acknowledges Examiner's response to the arguments. For the reasons set forth in Applicant's response of January 16, 2007, however, Applicant maintains that Allione neither teaches nor suggests determining which allele of the afflicted parent was inherited by the offspring, an element essential to the methods of the present invention. Neither Cohen nor Skolnick cure the deficiencies of Allione.

The Examiner contends that it would have been obvious to one of skill in the art at the time of the invention to "employ the teachings of Allione et al. and Cohen et al. for [a] method of determining the risk of an offspring of the patient for the same cancer, thereby arriving at the claimed invention..." (Office Action, page 6.) On the contrary, neither the combination of these studies, nor the combination of these studies with Skolnick, suggest the present method for diagnosis of offspring. As is indicated in the Declaration of Lan Kluwe provided herewith (Exhibit A), as of the June 27, 2000 priority date of the application, the typical manner of performing presymptomatic or prenatal diagnosis of tumor suppressor gene diseases was to undertake a mutation analysis of a DNA section coding for the characterizing gene for the phakomatotic tumor suppressor gene disease. These studies are extremely time consuming, taking on the order of several months in some cases and requiring invasive processes. Both of those aspects of mutational analysis are undesirable for prenatal testing. Occasionally, linkage analysis based on DNA fragments linked to the characterizing gene for the phakomatotic tumor suppressor gene disease was used to predict disease

in presymptomatic or pre-natal offspring. Linkage analysis, however, requires two affected family members and, thus, is not useful for many families. Accordingly, there was an urgent and long-felt but unmet need for improved methods for determining whether offspring of an afflicted individual had inherited the disease-causing allele. In contrast, the present method provides for diagnosis in a much more expedited timeframe (e.g., on the order of days or weeks) with only one affected family member. (See specification as originally filed, page 2, lines 19-24.) The rapidity with which the diagnosis can be completed using methods of the present invention is particularly critical for prenatal diagnosis. Given the advantages of diagnosis according to the present invention, had it been obvious at the time of filing of the present invention, the cumbersome, time consuming, and costly mutation analyses would not have been continually relied upon.

For at least the reasons set forth above, it was not obvious to one of skill in the art at the time of the present invention to combine the teachings of the cited documents. None of the cited documents either alone or in any combination teach or suggest the claimed invention.

Nevertheless, solely to expedite prosecution, Applicant has amended claim 19 to clarify that the tumor suppressor gene disease is a phakomatosis. As amended, claim 19 recites "A method for determining whether an offspring of an individual afflicted with a phakomatosis, wherein said phakomatosis is a tumor suppressor gene disease, has an increased risk of developing the tumor supporessor gene disease...." Support for this amendment can be found in the specification as orginally filed at page 1, lines 6-7.

Allione does not teach or suggest diagnosis of a phakomatosis, but rather relates exclusively to breast cancer. Neither Cohen nor Skolnick cure the deficiencies of Allione. The cited documents, thus, cannot render obvious the claimed invention. Applicant requests reconsideration and withdrawal of this rejection.

Provisional Obviousness-Type Double Patenting

Claims 2, 3, 8-10, 14, and 19 stand provisionally rejected for nonstatutory obviousness-type double patenting as "unpatentable" over claims 1-16 of U.S. Patent No. 6,660,477, for reasons detailed in the August 15, 2006 Office Action.

Applicants stand ready to file a Terminal Disclaimer upon the Examiner's indication of allowable subject matter in this application.

CONCLUSION

In view of the foregoing amendments and remarks, applicants respectfully request that the Examiner withdraw all the objections and rejections and allow all of the claims of this application.

Respectfully submitted,

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